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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,381

Applicant(s)

FIGUEROA ET AL.

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly amended claim 34 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 34 now requires identifying a desired surface-to-mass ratio and applying dots to achieve the desired surface-to-mass ratio, whereas the originally-filed claims and those embodied now in the invention of claims 1-10 and 29-33 are directed to a process of identifying a desired dissolution rate and applying dots to achieve the desired dissolution rate. While claim 34 did previously outline a process of controlling dissolution rates by applying dots to achieve a desired surface-to-mass ratio, the achievement was argued by Examiner to be inherent and there were previously no claimed active method step of selecting a desired surface-to-mass ratio. These inventions now embody independent and distinct method limitations.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 34 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

2. Claims 1, 4, 6-8, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8, 12-13, 15-16, 32-34, 37-40, 42, 43, and 46 of copending Application No. 10/801,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because both require dot placement to achieve a desired dissolution rate. While the copending application claims are sometimes broader in scope, the dependent claims (see claim 46) outline dot pattern as an application parameter to control dissolution rate.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 4-6, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6, 36, and 29 of copending Application No. 10/801,379. Although the conflicting claims are not identical, they are not patentably distinct from each other because the selection of the dot topography of the '379 application inherently requires selecting the position of a first and second drop.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3, 6-8, 29-30, and 32-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Voss et al. (4,322,449).

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern (abstract; throughout; col. 5, lines 35-37). Voss teaches the control of various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. As is known in the art and as taught in the specification, controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control.

As for the newly-added limitation of first "identifying a target dissolution rate", Examiner notes that safe and effective administration of a drug (bioactive agent) to a patient requires a precise dose at an acceptable "target" dissolution rate. Medical professionals, such as doctors, pharmacists, and pharmaceutical company scientists, are of ordinary skill in this art. Medical personnel would have been aware that a too-rapid dissolution rate could lead to an over-dose, whereas a too-slow dissolution rate could lead to ineffective treatment levels. Neither of these risks is acceptable. Also, many medications are provided in a controlled release (CR) form to provide the correct dose over a period of time, inherently requiring the use of a target dissolution rate.

Therefore, when creating a drug delivery substrate, it is Examiner's position that it would

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have been inherent for one of ordinary skill in the art to identify, in addition to a desired target dose, a target dissolution rate. The patterns of dots placed down on the delivery substrate of Voss would have been inherently placed to achieve said target dissolution rate for the safety and health of medical patients.

In the alternative, for all the reasons stated above, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to select a target dissolution rate to be achieved by the patterns of Voss to ensure the safe and effective administration of drugs to patients.

One of ordinary skill in the art would have been well aware of the effects of surface area on dissolution rate, for example, that a plurality of small thin dots would dissolve faster than a thick, large dot. As evidence of this awareness, as outlined above, Voss teaches control of the parameters that would be known by ordinary artisans in the medical coating art to impact dissolution rate.

Voss teaches the use of a piezoelectric ejection element (abstract) with a number of nozzles (col. 4, line 18).

Voss provides the bioactive agent in a solvent (col. 5, lines 52-62), which inherently dries by evaporation, with precisely controlled concentration and drop volume (col. 6, line 5).

Voss refers to some dots as being discrete, with a specified volume. Dots are "spaced". Voss also uses his method to write letters (Ex. 2), requiring, in some instances, at least a partial overlap of dots.

Regarding claim 3, requiring sufficient spacing to avoid coalescing, Voss' method of creating spaced, discrete dots sufficiently spaces the dots.

Claim 29 is added to this rejection for the same reasons that Voss is applied to claim 1. Voss' control over various parameters will inherently achieve the dissolution rate.

Claim 30 is rejected for the same reasons as claim 2.

Claim 32 is rejected for the same reasons as claim 3.

The substrate of Voss is ingestible (see Examples).

Claim Rejections - 35 USC § 103

9. Claims 9-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss.

Voss teaches that which is disclosed above, but fails to specifically teach the standard deviation regarding the spacing or overlapping of droplets. However, Voss goes to great lengths to discuss the precision, uniformity, and reproducibility of the dot sizes, dosages, and concentrations he applies. Because a plate of nozzles may be used in a fixed arrangement, the dots formed should always be spaced the same, i.e., with a deviation approaching zero percent. It would have been obvious to an ordinary artisan wishing to achieve uniformity and precision in dosing to select and maintain a spacing that is consistent from dot to dot, i.e., with a standard deviation of less than 15%.

While achieving perfect uniformity is impossible, Voss' teachings clearly direct one of ordinary skill in the art to precisely space the dots with *no standard deviation*, i.e., with a deviation approaching 0%, which would be less than 15%. Voss creates dosage zones

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on his ingestible substrate with specific dosage ratios. Incorrect spacing would yield a zone with too many or too few dosage dots, leading to dosage error. Likewise, in creating letters, another embodiment of Voss, a uniform spacing of the dots which create the letters would be necessary to yield letters with smooth lines (letters made of dots with varying spacing would be thicker in some areas).

It is well settled that determination of optimum values of cause effective variables such as standard deviation is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 31, it is Examiner's position that in the creation of letters or other desired geometric patterns, Voss will desirably select a second dot to fully overlap a first dot to create a larger dot in a given location. It would have been within the skill of an ordinary artisan to "fully" overlap one dot with another if a larger "ink" spot is needed to create a letter, such as in, for example, dotting an "i".

10. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

Voss teaches that which is disclosed above, namely forming droplets of bioactive agent using piezoelectric ejection elements. What Voss does not teach is the use of thermal ejection elements.

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It is Examiner's position that these two species of inkjet printing are obvious variants that would have been known to an ordinary artisan and cites Voges for teaching the same.

Voges teaches a method of forming droplets of bioactive agent by using one of the two forms of inkjet printing, namely either a piezoelectric ejection device or a thermal ejection device.

Since Voss teaches printing precise drops of bioactive agent using a piezoelectric element, such as is used in inkjet printing, and Voges teaches that either the piezoelectric or thermal types of inkjet printing are suitable for forming precise droplets of bioactive agent, Voges would have reasonably suggested the use of a thermal element in the method of Voss. It would have been obvious to one of ordinary skill in the art to use the interchangeability teachings of Voges in the method of Voss to provide Voss with a suitable, successful alternative element for dosing dots in a precise manner. Like Voss, Voges teaches a plurality of nozzles or ejection orifices that provide uniformly-sized droplets.

Response to Arguments

11. Applicant's arguments filed 6/12/2006 have been fully considered but they are not persuasive.

Many of the arguments have been addressed above, in the body of the rejections.

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Applicant argues that Examiner has not considered the placement of the second drop in relation to the first based on a target dissolution rate.

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern. A desired pattern of dots indicates a decision was made to select a specific pattern and location of all dots, the first, second, and subsequent ones.

Applicant finds the references deficient because they do not explicitly require identifying target dissolution rates.

The safe and effective administration of drugs requires correct quantities (i.e., dose) at correct rates of administration (i.e., dissolution rates). Any pattern selected in the use of the Voss reference must be selected based on dose and rate. A delivery substrate pattern yielding the incorrect dose and/or dose rate would be unacceptable. One of ordinary skill in the art must have these two factors in mind when creating a pattern of drug dots and when testing the delivery substrate. Even if the dose and dose rate are only tested in R&D after manufacture (but before sale), using a trial-and-error method, one of ordinary skill in the art must still have a desired target dose/dissolution rate in mind, i.e., one that was "identified". In fact, Applicant's own specification states that "a desired dissolution rate can be discovered through experimentation, in which one or more application parameters are varied until a desired dissolution rate is achieved" and that drop size, nozzle size, solution concentration, drying temperatures, and drop pattern are all appropriate parameters to vary (p. 20). These parameters would have all

been well-known by one of ordinary skill in the medical coating and administering art to impact the rate at which a coating would dissolve from a substrate.

Further Voss teaches the control of these various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. Examiner maintains that controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently and/or obviously provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control, which is imperative to safe dosing of bioactive agents. When dosing a patient, a physician inherently considers the amount of therapeutic agent in addition to the rate at which the dose is administered.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer K. Michener
Primary Examiner
Art Unit 1762

jkm